

Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (Text with EEA relevance)

*Article 2*

**Amendments to Regulation (EC) No 1829/2003**

Regulation (EC) No 1829/2003 is amended as follows:

- (1) in Article 5, paragraph 3 is amended as follows:
  - (a) the introductory wording is replaced by the following:

The application shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, and shall be accompanied by the following;
  - (b) point (l) is replaced by the following:
    - (l) an identification of the parts of the application and any other supplementary information that the applicant requests to be treated as confidential, accompanied by verifiable justification, pursuant to Article 30 of this Regulation and Article 39 of Regulation (EC) No 178/2002;;
  - (c) the following point is added:
    - (m) a summary of the dossier in a standardised form.;
- (2) in Article 6, paragraph 7 is replaced by the following:

7. The Authority, in accordance with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public, after deletion of any information identified as confidential in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002 and Article 30 of this Regulation. The public may make comments to the Commission within 30 days of such publication.;
- (3) in Article 10, paragraph 1 is replaced by the following:
  1. On its own initiative or following a request from the Commission or from a Member State, the Authority shall issue an opinion on whether an authorisation for a product referred to in Article 3(1) of this Regulation still meets the conditions set out in this Regulation. It shall forthwith transmit that opinion to the Commission, Member States and the authorisation-holder. The Authority, in accordance with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public, after deletion of any information identified as confidential in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002 and Article 30 of this Regulation. The public may make comments to the Commission within 30 days of such publication.;
- (4) in Article 11(2), the introductory wording is replaced by the following:

2. The application shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, and accompanied by the following::
- (5) in Article 17, paragraph 3 is amended as follows:
- (a) the introductory wording is replaced by the following:
- The application shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, and accompanied by the following::
- (b) point (l) is replaced by the following:
- (l) an identification of the parts of the application and any other supplementary information that the applicant requests to be treated as confidential, accompanied by verifiable justification, pursuant to Article 30 of this Regulation and Articles 39 to 39e of Regulation (EC) No 178/2002;;
- (c) the following point is added:
- (m) a summary of the dossier in a standardised form.;
- (6) in Article 18, paragraph 7 is replaced by the following:
7. The Authority shall, in accordance with Article 38(1) of Regulation (EC) No 178/2002, make its opinion public, after the deletion of any information identified as confidential in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002 and Article 30 of this Regulation. The public may make comments to the Commission within 30 days of such publication.;
- (7) in Article 22, paragraph 1 is replaced by the following:
1. On its own initiative or following a request from the Commission or from a Member State, the Authority shall issue an opinion on whether an authorisation for a product referred to in Article 15(1) still meets the conditions set out in this Regulation. It shall forthwith transmit that opinion to the Commission, Member States and the authorisation-holder. The Authority, in accordance with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public, after deletion of any information identified as confidential in accordance with Articles 39 to 39e of Regulation (EC) No 178/2002 and Article 30 of this Regulation. The public may make comments to the Commission within 30 days of such publication.;
- (8) in Article 23(2), the introductory wording is replaced by the following:
2. The application shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, and accompanied by the following::
- (9) in Article 29, paragraphs 1 and 2 are replaced by the following:
1. The Authority shall make public the application for authorisation, relevant supporting information and any supplementary information supplied by the applicant, as well as its scientific opinions and opinions from the competent authorities referred to in Article 4 of Directive 2001/18/EC, in accordance with Articles 38 to 39e of Regulation (EC) No 178/2002 and taking into account Article 30 of this Regulation.

2                   The Authority shall apply Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents<sup>(1)</sup> when handling applications for access to documents held by the Authority.;

(10) Article 30 is replaced by the following:

*Article 30*

**Confidentiality**

1                   In accordance with the conditions and the procedures laid down in Articles 39 to 39e of Regulation (EC) No 178/2002 and this Article:

- a the applicant may submit a request to treat certain parts of the information submitted under this Regulation as confidential, accompanied by verifiable justification; and
- b the Authority shall assess the confidentiality request submitted by the applicant.

2                   In addition to the items of information referred to in points (a), (b) and (c) of Article 39(2) of Regulation (EC) No 178/2002 and pursuant to Article 39(3) thereof, the Authority may also grant confidential treatment with respect to the following information, where the disclosure of such information is demonstrated by the applicant to potentially harm its interests to a significant degree:

- a DNA sequence information, except for sequences used for the purpose of detection, identification and quantification of the transformation event; and
- b breeding patterns and strategies.

3                   The use of the detection methods and the reproduction of the reference materials, provided under Articles 5(3) and 17(3) for the purpose of applying this Regulation to GMOs, food or feed to which an application refers, shall not be restricted by the exercise of intellectual property rights or otherwise.

4                   This Article is without prejudice to Article 41 of Regulation (EC) No 178/2002..

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*Status: This is the original version (as it was originally adopted).*

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- (1) Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents ([OJ L 145, 31.5.2001, p. 43](#)).?;